Remarks

Amendments to the Claims

The amendments to the claims do not add new matter. Independent claims 1-3 are amended to include a step of measuring the effect of the test compound on a symptom of the disease in an *in vivo* assay; the specification supports this recitation on page 40, lines 9-13.

Rejection Under 35 U.S.C. § 112 ¶ 1 (enablement)

Claims 1-4, 6-11, 25, and 27-30 are rejected under 35 U.S.C. § 112 ¶ 1 as not enabled because "the skilled artisan would not be able to predict whether or not a modulator of an NPFF-1 activity (such as alteration of intracellular calcium) could be used to treat a cardiovascular disease." Final Office Action at page 4, first full paragraph. Claims 27 and 29 are canceled. Applicants respectfully traverse the rejection of claims 1-4, 6-11, 25, 28, and 30.

The Examiner has the initial burden to establish a reasonable basis to question the enablement provided in the specification. *In re Wright*, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). Claims 1-4, 6-11, 25, 28, and 30 are directed to screening methods. None of the claims recites, requires, or encompasses treatment of any disease, including any cardiovascular disease. None of the claims requires that the tested compounds produce a desirable clinical effect. It is well known that not all agents identified in a screening method will become therapeutics, and the claims do not require confirmation that the recited test compounds actually can be used to treat any of the recited diseases.

The Final Office Action does not provide a reasonable basis to question the enablement of the claimed screening methods. Please withdraw the rejection.

Rejection Under 35 U.S.C. § 112 ¶ 1 (written description)

Claims 1-4, 6-11, 25, and 27-30 are rejected under 35 U.S.C. § 112 ¶ 1 as failing to comply with the written description requirement. Claims 27 and 29 are canceled. Applicants respectfully traverse the rejection of claims 1-4, 6-11, 25, 28, and 30.

The Final Office Action contends that the specification does not describe the genus of recited NPFF1 polypeptides because the specification teaches that an "NPFF1 polypeptide" includes variants which show at least 80% homology to SEQ ID NO:2. This teaching in the specification is not relevant to the invention as now claimed. The first step in a written description inquiry is to construe the claims properly. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991). Each of independent claims 1, 2, and 3 recites a "human NPFF1 polypeptide." It is a fundamental rule of claim construction that every limitation is material and that what is claimed is what is defined by the claim as a whole. *General Foods Corp. v. Studiengesellschaft Kohle GmbH*, 972 F.2d 1272, 1280, 23 U.S.P.Q.2d 1839, 1345 (Fed. Cir. 1992). It is improper to import a broad definition from the specification into a claim. M.P.E.P. § 2111.01. By their plain language, the pending claims encompass only human NPFF1 polypeptides.

Moreover, even the cited portions of the specification do not support the asserted scope of the recited human NPFF1 polypeptides. The specification defines an "NPFF1 polypeptide" as a polypeptide "selected from a group consisting of" polypeptides having the sequence of SEQ ID NO: 2, polypeptides comprising the sequence of SEQ ID NO: 2, (iii) polypeptides encoded by NPFF1 polynucleotides; and (iv) polypeptides which show at least 99%, 98%, 95%, 90%, or 80% homology with a polypeptide of (i), (ii), or (iii); wherein said polypeptide has NPFF1 activity. See paragraph [0037] of the published application.

The Final Office Action sets forth no evidence that the genus of human NPFF1 polypeptides is so varied that the specification does not describe it. A specification adequately describes a genus if it permits the skilled artisan to "visualize or recognize members of the genus." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). The specification describes a human NPFF1 polypeptide comprising the amino acid sequence SEQ ID NO:2. Because human NPFF1 polypeptides are highly conserved, the species of SEQ ID NO:2 represents the genus of human NPFF1 polypeptides.

Attachment 1 is a BLAST search of human protein sequences using SEQ ID NO:2 as the query. SEQ ID NO:2 is 430 amino acids in length. As summarized in the table below, the top 10 search results are proteins that are identical to or nearly identical to SEQ ID NO:2 and are assigned the GENE ID 64106 (NFPP1), whereas the next most similar search result is only 56% identical over 348 amino acids and, in fact, is identified as a different protein (neuropeptide FF receptor 2 isoform 2).

Accession Nos.	length	% identity to SEQ ID NO:2	GENE ID
NP_071429	430	100% over 430 amino acids	64106 (NFPP1)
Q9GZQ6	430	100% over 430 amino acids	64106 (NFPP1)
AAG41397	430	100% over 430 amino acids	64106 (NFPP1)
BAB17677	430	100% over 430 amino acids	64106 (NFPP1)
AAI31581	430	100% over 430 amino acids	64106 (NFPP1)
ABY87927	430	100% over 430 amino acids	64106 (NFPP1)
BAC05950	441	100% over 429 amino acids	64106 (NFPP1)
AAK94199	430	100% over 429 amino acids	64106 (NFPP1)
CAI12599	428	100% over 428 amino acids	64106 (NFPP1)
EAW54387	386	100% over 386 amino acids	64106 (NFPP1)
NP_444264	420	56% over 348 amino acids	10886 (NFPP2)

Thus, the protein comprising SEQ ID NO:2 as disclosed in the specification represents the genus of human NPFF1 polypeptides. "The burden of showing that the claimed invention is not

described in the application rests on the PTO in the first instance." *In re Edwards*, 568 F.2d, 1349, 1354 (C.C.P.A. 1978). The Final Office Action provides no reasons at all why, in view of the disclosure of the application as filed, a person skilled in the art at the application's priority date would not have recognized that the inventors possessed the invention of claims 1-4, 6-11, 25, 28, and 30.

When the claims are properly interpreted as limited to human NPFF1 polypeptides, and because SEQ ID NO:2 represents the genus of human NPFF1 polypeptides, it is clear that the specification sufficiently describes the claimed subject matter. Please withdraw the rejection.

Rejection of Claims 1-4, 6-11, 28, and 30 Under 35 U.S.C. § 102(b)

The Office Action rejects claims 1-4, 6-11, 28, and 30 under 35 U.S.C. § 102(b) as anticipated by Bonini *et al.* (*J. Biol. Chem. 275*, 39324-31, 2000). Applicants respectfully traverse the rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claimed invention. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). Bonini does not meet this standard.

Independent claims 1, 2, and 3 as amended recite a step of measuring the effect of the test compound on a symptom of the disease in an *in vivo* assay. Bonini does not teach such a step. Thus, Bonini does not teach every element of independent claims 1-3 and therefore does not anticipate claims 1-4, 6-11, 28, or 38.

Please withdraw the rejection.

Objection to Claim 3

Claim 3 is objected to because of an extraneous word in line 11. The amendments to claim 3 moot the objection.

Rejection of Claims 27 and 29 Under 35 U.S.C. § 112 ¶ 1 (new matter)

Claims 27 and 29 are rejected 35 U.S.C. § 112 ¶ 1 as containing new matter. Claims 27 and 29 are canceled to advance prosecution.

Respectfully submitted,

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